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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,367	08/31/2006	Darin G. Schaeffer	8627-1246 (PA-5595-PCT/US)	8070
48093 7590 09/27/2010 BRINKS HOFER GILSON & LIONE/CHICAGO/COOK PO BOX 10395 CHICAGO, IL 60610				
EXAMINER DOWE, KATHERINE MARIE				
ART UNIT		PAPER NUMBER		
3734				
MAIL DATE		DELIVERY MODE		
09/27/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/591,367

Applicant(s)

SCHAEFFER, DARIN G.

Examiner

KATHERINE M. DOWE

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The following is a complete response to the amendment filed July 9, 2010.
2. Claims 1-25 and 27-29 are currently pending.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-4, 22-25, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Patel (US 4,784,639). Regarding claims 1 and 22, Patel discloses a catheter (11) comprising an elongate flexible catheter tip (23) disposed at a distal end of the catheter (Fig 1). A longitudinally compressible, accordion-type corrugated region (23) is located between the proximal tip end (19) and the distal tip end (29). A wall thickness of the corrugated region is substantially the same as a wall thickness of the proximal and distal ends (Fig 3).

Regarding claims 2 and 3, the flexible tip comprises a tube member that defines a lumen extending longitudinally throughout the elongate flexible tip body (Fig 3).

Regarding claim 4, the catheter comprises a rounded distal end (Fig 1).

Regarding claims 23-25 and 28, the corrugated region comprises a plurality of ridges interspersed with a plurality of grooves. The ridges have an outer diameter that is greater than an outer diameter of the proximal and distal tip ends and the grooves have an inner diameter that is substantially the same as an inner diameter of the proximal and distal tip ends (Fig 3).

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel (US 4,784,639). Patel discloses the claimed invention, as shown above, except for the material of the flexible tip. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of Patel such that the elongate flexible tip comprised a material selected from the group consisting of nylon, polyether-block co-polyamide polymers, polyethylene, polyvinyl chloride, polystyrene, silicon co-polymer, polyolefin, polyurethane, and combinations thereof, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel (US 4,784,639) in view of Elkins et al. (US 6,994,700, hereinafter "Elkins"). Patel discloses the claimed invention, as shown above, including a corrugated region having a plurality of ridges and grooves, wherein the ridges have an outer diameter that is greater than an outer diameter of the proximal and distal tip ends (Fig 3). However, Patel does not disclose the grooves have an inner diameter that is smaller than an inner diameter of the proximal and distal tip ends. Elkins discloses a catheter having a corrugated region (222) with a plurality of ridges and grooves (Figs 15a-16b). The ridges have an outer diameter that is greater than an outer diameter of the tube member extending from the corrugated region (Figs 15a-16b). The grooves may have an inner diameter that is approximately the same as an inner diameter of the proximal and distal catheter ends (Fig 15b) or the grooves may have an inner diameter that is smaller than an inner diameter an inner diameter of the proximal and distal catheter ends (Fig 16b). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Patel such that the inner diameter of the

grooves was smaller than the inner diameter of the proximal and distal tip ends, since such a configuration is a known alternative and may impart additional flexibility to the tip.

8. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel (US 4,784,639) in view of Ferrara (US 4,995,872). Patel discloses the claimed invention, as shown above, including a corrugated region. However, Patel teaches the corrugated region is circular and does not disclose the corrugated region comprises a helical corrugation. Ferrara disclose a catheter with a corrugated region (36) and teach, "In view of the foregoing descriptions, it will be apparent that circular corrugations in expandable section 36 of catheter means 32 are preferred. However, other than the specifically described corrugation shapes can be used instead; for example, different fold shapes and orientations and, for instance, helical corrugations" (col 5, ll 24-29). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Patel such that the corrugated region comprised a helical corrugation, since such a configuration is a known functional equivalent.

9. Claims 1, 5-7, 11, 13-15, and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijay et al. (WO 89/02763, hereinafter "Wijay") in view of Patel (US 4,784,639). Regarding claims 1 and 5, Wijay discloses the invention substantially as claimed including a flexible tip (T), wherein the proximal tip end is adjacently attached to an inner distal end of a dilation catheter (Fig 1). The dilation catheter comprises an elongate outer body (B), an elongate inner body (I), and a balloon (D). The inner body (I) has a proximal region (20) located within the outer body (B) and extends between the proximal and distal ends of the outer body (B). The inner body (I) has a distal region extending past the distal end (62) of the outer

body (B). The balloon (D) comprises a proximal balloon leg attached to the distal end of the outer body (B) and a distal balloon leg attached to a distal end of the dilation catheter. A balloon cavity (24) defined by the proximal and distal balloon legs is in fluid communication with the outer lumen (pg 11, ll 20-34).

However, Wijay does not disclose the flexible tip (T) comprises a corrugated region. Patel discloses a catheter with a flexible tip having a corrugated region (23). The corrugated region is longitudinally compressible and has a wall thickness substantially the same as a wall thickness of the proximal and distal ends of the tip (Fig 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wijay set that the flexible tip was corrugated to ensure the tip portion was sufficiently flexible to prevent damage to the vessel as the catheter is directed through the vasculature.

Regarding claim 6, the proximal tip end is attached to the distal end of the inner body (I) at a tip end attachment (34) and the distal balloon leg (32) is attached across the tip-end attachment (Fig 1). The distal tip end is rounded (Fig 1).

Regarding claim 7, the distal balloon leg (32) may be attached to the distal region proximal to the tip-end attachment (Fig 2).

Regarding claims 11 and 19, the distal balloon leg (32) is attached to the inner distal end (I) providing a distal bonding region, wherein the bonding region has a distal face circumscribing the inner distal end and the proximal tip end (T) is attached to the distal body end via the distal face (Fig 1).

Regarding claims 13 and 14, the distal balloon leg (32) is attached to the distal region, such that the distal region extends beyond the balloon leg and comprises an external mounting shoulder about which the flexible tip (T) is attached (Fig 2).

Regarding claim 15, a tip lumen (14) is defined by the flexible tip (T), wherein the lumen is aligned with a wire guide lumen (12). The wire guide lumen (12) and inflation lumen (A/24) are parallel (Fig 1).

Regarding claims 17 and 18, the proximal tip end (T) is adjacently attached to the distal body end forming a tip-end attachment (34); the distal balloon leg (32) is adjacently attached to the distal body end, the proximal tip end, and the tip-end attachment; and the distal tip (T) is integral with a rounded distal end (Fig 1).

Regarding claims 20 and 21, the distal balloon leg (32) is adjacently attached to the distal body end, forming an external mounting shoulder. The proximal tip end (T) is adjacently attached to the distal body end and the distal balloon leg via the external mounting shoulder (Fig 2).

10. Claims 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijay (WO 89/02763) and Patel (US 4,784,639), as applied to claim 5 above, further in view of Crocker (US 5,542,926). Regarding claims 8, 9, and 12, Wijay and Patel disclose the invention substantially as claimed as shown above. However, Wijay does not disclose the elongated inner body comprises a braided coil reinforcing member. Crocker discloses a similar catheter comprising an elongate body (50) and teaches the body is reinforced by embedding a braided material or coil (51) within body (Fig 6; col 8, ll 5-18). The coil comprises a high strength material such as stainless steel or platinum wire, thus the inner body has a lower durometer than the inner coil material (col 8, ll 5-18). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wijay such that a coil of higher durometer material was embedded within the inner body to reinforce the column strength of the inner member and improve the pushability of the catheter.

Regarding claim 10, Crocker teaches the coil may be tightly wound or loosely wound depending on the desired flexibility (col 8, ll 25-35). Therefore, it would have been obvious to modify the combination of Wijay, Patel, and Crocker such that the braided coil was of varying tightness throughout the inner body to vary the flexibility of the inner body as desired.

Response to Arguments

11. Applicant's arguments, see amendment, filed July 9, 2010, with respect to the rejection of claims under Stevens (US 5,514,108), Schwartz (US 5,437,288), and Elkins (US 6,994,700) have been fully considered and are persuasive. Stevens and Schwartz do not disclose the corrugated region is longitudinally compressible and has a uniform wall thickness. Elkins does not disclose a catheter tip with a corrugated region located at the distal end of the catheter. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Patel (US 4,784,639).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
September 23, 2010

/K. M. D./
Examiner, Art Unit 3734

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